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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/507,108	02/17/2000	Mary M. Swenson	54682 USA 6A	7637
32692	7590	08/16/2004		
3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427				
			EXAMINER LEWIS, KIM M	
			ART UNIT 3743	PAPER NUMBER

DATE MAILED: 08/16/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/507,108

Applicant(s)

SWENSON, MARY · M.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☒ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 21.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action.

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## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment filed on 1/20/04 has been received and made of record in the application file wrapper. Claim 1 and 16 have been amended and claims 36-38 have been added.
2. Claims 1-38 are pending in the instant application.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 1/20/04 has been received. Note the acknowledged form PTO-1449 enclosed herewith.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1, 10-12, 15, 16, 18, 19, 22, 23, 30 and 36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,409,472 ("Rawlings et al.")

Prior to beginning claim analysis, the examiner wishes to point out that the specification on page 5, lines 31-22 recites the following:

"[p]referred foams are also substantially nonswellable. In this context, "substantially nonswellable" means that there is little or no increase in volume of the foam upon absorption of water or saline, and hence, exudate from a wound".

Then on page 6, lines 24-31, the specification recites:

"[e]xamples of suitable material for the absorbent, substantially nonswellable foams include synthetic organic polymers including, but not limited to: polyurethanes, carboxylated butadiene-styrene rubbers, polyesters, and polyacrylates. The polymeric foams can be made of one or more types of monomers (e.g. copolymers) or mixtures (e.g. blends) of polymers. Preferred foam materials are polyurethanes. A particularly preferred foam is a polyurethane, available under the trade designation POLYCRIL400 from Fulflex, Inc., Middleton, R.I."

In light of the above-recited paragraphs, Rawlings et al. anticipate the invention of claim 1 as presently claimed. More specifically, Rawlings et al. disclose a medical article in the form of an adhesive polymeric dressing comprising a liquid impervious, water-vapor permeable film material (col. 8, lines 65-66 and col. 12, lines 65-66) having directly bonded thereto an absorbent foam.

Rawlings et al. further disclose apt foams constructed from "polyurethane, carboxylated butadiene styrene rubber, polyacrylate or like foam. Such foams may be made of hydrophilic materials *per se* or may be treated to render them hydrophilic, for

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example, with surfactants" (col. 6, line 58-67). Similarly, the applicant on page 6, lines 24+ disclose the same absorbent foams.

Rawlings et al. fail to explicitly disclose that the foam is substantially nonswellable and that the foam comprises a hydrophobic polymer.

Since the applicant fails to disclose in both the specification and claims anything that would chemically or physically alter the disclosed absorbent foams in order to render them nonswellable, the examiner contends that the nonswellable feature of the foams is an inherent characteristic of the foam. It then follows that the same foams disclosed by Rawlings et al. have the same inherent nonswellable characteristic. Also, it is inherent that if the surfactant is placed on a foam to render it hydrophilic, it must be hydrophobic.

Assuming arguendo that the applicant disagrees with this rationale, the examiner contends that one having ordinary skill would have found it within the level of ordinary skill to apply use nonswellable foams on a wound in order to prevent the foam from swelling and applying pressure to the wound site once exudate has been absorbed.

As regards claim 10, the polymeric film is a layer.

As regards claim 11, note col. 9, lines 5-20, which discloses the permeability of the film.

As regards claim 12, note col. 9, lines 47-48, which discloses the thickness of the film.

As regards claims 15 and 16, note col. 6, lines 42-47 and lines 58-59, which disclose the type of foam used.

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As regards claims 18 and 19, note Fig. 1, which discloses that the film extends beyond the periphery of the foam and an adhesive there around.

As regards claim 22, note col. 12, lines 38-45, which discloses how the foam is adhered to the film.

As regards claim 23, note the abstract, which discloses that the device is a wound dressing.

As regards claim 36, note the rejection of claim 1 above.

7. Claims 2-9, 13-14, 24-32, 34, 35, 37, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rawlings et al.

As regards claims, 13-14, 25-27 and 29 Rawlings et al. fail to disclose the claimed wet and dry MVTRs, the claimed NaCl absorbing amounts, and the claimed increases in volume. It would have been an obvious matter of design choice to modify the device of Rawlings et al. to include the claimed wet and dry MVTRs, NaCl absorbing amounts, and the claimed increases in volume, since the applicant has not disclosed that the particulars solve any stated problem or are for any particular purpose, and it appears that the invention would perform equally well with different wet and dry MVTRs, NaCl absorbing amounts, and volume increases. Accordingly, constructing the device of Rawlings et al. to include these limitations is deemed an design consideration, which fails to patentably distinguish applicant's invention.

As regards claim 24, note the rejection of claims 1-3 above.

As regards claim 28, the polymeric film is a layer.

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As regards claim 30, note the rejection of claims 15 and 16 above.

As regards claim 31, note the rejection of claims 18 and 24 above.

As regards claim 32, note the rejection of claims 19 and 24 above.

As regards claim 34, note the rejection of claim 24 and col. 12, lines 38-45, which discloses casting of the film and foam.

As regards claim 35, the device disclosed by Rawlings et al. is a wound dressing abstract).

As regards claim 37, note the rejection of claim 1 above.

As regards claim 38, note the rejection of claims 1, 8 and 13 above.

8. Claims 10, 17, 20, 21, 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rawlings et al. in view of U.S. Patent No. 5,000,172 ("Ward").

As regards claims 10, 20, 28 and 33, Rawlings et al. fail to disclose that the film layer comprises one or more layers. However, Ward teaches it is known to construct backing layers (film layers) with additional film layers (nonwoven) for support. It would have been obvious to one having ordinary skill in the art to modify Rawlings et al. by constructing the film layer from one or more layers for additional support, as suggested by Ward.

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As regards claim 17, Rawlings et al. fail to disclose graphics on the film material. However, Ward teaches it is known to provide graphics on the film layer of a bandage in order to monitor the size of a wound. It would have been obvious to one having ordinary skill in the art to modify Rawlings et al. with the addition of graphics on the film layer, as suggested by Ward, in order to monitor the size of a wound.

As regards claim 21, Ward discloses that the additional layer is adhesively bonded to the backing layer. Ward fails to teach the adhesive used is a fibrous adhesive. Absent a critical teaching and/or a showing of unexpected results derived from the use of a fibrous adhesive, the examiner contend that the type of adhesive used is an obvious design choice which does not patentably distinguish applicant's invention.

### ***Response to Arguments***

9. Applicant's arguments filed 1/20/24 have been fully considered but they are not persuasive. In response to applicant's argument that Rawlings et al. disclose that it is much preferred to use foams which are made of a polymer which is itself hydrophilic as it has been found that the exudate is less likely to coagulate rapidly, and that Rawlings et al. disclose dressings using foams made of hydrophilic polymers, which would be inherently swellable, the examiner agrees. However, it must be noted that although Rawlings et al. prefer the use of hydrophilic foams, Rawlings et al. also disclose the use of foams made hydrophilic by the application of a surfactant thereto. These foams are inherently hydrophobic and inherently nonswellable.

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Furthermore, the applicant discloses in the specification that the foams of the instant invention are also hydrophobic foams treated with a surfactant to render them hydrophilic. This is essentially the same disclosure as that of Rawlings et al.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Monday -Wednesday from 5:30 am to 4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703.308.0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis  
Primary Examiner  
Art Unit 3743

Kml  
April 5, 2004